

OPTN Policies Plain Language Rewrite

Overview

Member surveys and other feedback have long noted the complex wording and organization of OPTN policies. The OPTN Policies Plain Language Rewrite addresses these concerns. Our aim is to make the documents more readable and easier for transplant professionals, patients, and the public to understand and use. It also will help establish clarity and organizational standards for future OPTN materials. Revisions made as part of this rewrite are only intended to affect organization and writing, and should not alter the substance or meaning of the existing material. The reorganization should help the transplant community to more quickly and easily find the information needed.

Rewrite Process

The OPTN Policy Plain Language Rewrite proposal was first offered for public comment in July 2012. After collecting and analyzing all the comments submitted, UNOS staff made revisions to the policies including changes in style, formatting, terminology, and organization. This includes identifying many requested changes that would require substantive changes to the Policies and therefore cannot be addressed as part of this plain language rewrite. These items requiring substantive changes have been added to a “parking lot,” to be subsequently reviewed and addressed by OPTN/UNOS Committees.

The Plain Language Policy Rewrite is intended to only clarify and reorganize existing language. This rewrite aims to *not* make any substantive changes to the content or member requirements of the current Policies, but only changes the current language to make it easier to understand with more consistent terminology, better organization, and new usability features, including a table of contents.

Features of this document:

- Hyper-linked main table of contents, and a table of contents for each individual Policy.
- Two crosswalks:
 - A “built-in” crosswalk that identifies at the headings of the rewrite the current Policy number for easy comparison of the current language with the rewritten language.
 - A separate crosswalk at the end of the policies that tracks for each current Policy number where that Policy can be found in the Rewrite. Many of these references have hyperlinks to the current Policy on the OPTN website.
- Policies contained in a single, searchable document.
- More tables and lists for readability.
- Cross-references with hyperlinks that take readers directly to the cross-referenced Policy.
- Headers and footers with Policy titles and page numbers for reference.
- Comprehensive index.
- A *History* section with changes for each Policy including hyperlinks to the Policy notice that resulted in the change (where available).
- A *Notes* section to guide the reader to related information.

Hint: After clicking on a hyperlink that takes you to a different place in the document, you can press the **Alt + left arrow** keys to quickly return to your original place in the document.

What You Need to Know

Policy numbers and titles have changed. Members responsible for compliance with OPTN Policy need to be aware of the new policy numbers and titles and the need to update documents, forms, or other materials used at their institution. Detailed crosswalks are included at the end of the policy proposal to assist you in identifying these changes. If the rewritten policies are approved, UNOS staff will update the Evaluation Plan to reflect the new policy numbers and titles.

What We Need From You

- The public is invited to review proposed changes and to provide input through a brief, web-based survey. The survey and specially-designed website will allow you to access a document that catalogs the changes for each section of the rewritten policies.
- view the rewritten language and the current language as responses are submitted to the survey.
- comment for every section individually, only certain sections, or for the entire document.

Since the rewrite is intended to only clarify and reorganize existing language, please comment on whether the new language accurately reflects the old language, if it is easier to locate information, and if it's easier to understand. Reviewers may also directly comment on the rewrite by sending an email to publiccomment@unos.org.

The review of policies will be open from July 2-August 31, 2012. After the public comment period closes, UNOS will compile the feedback and make additional changes, in consultation with appropriate committees and staff. Revised and reformatted documents will then be presented to the OPTN Board of Directors for final approval.

Summary of the Rewrite by Policy:

- **Policy 1: Administrative Rules and Definitions**

This Policy contains some of the administrative rules and definitions for the policies. The information in the current Policy 1 was information that was already available in the bylaws so it was not retained in the Rewrite. Some other changes include:

- Rules of construction were added to explain some of the rules and drafting principles used in the Policies.
- All of the definitions were centralized into one location. Most of these definitions came from the current Policy 3.1. It is important to note that this is not a glossary. It only contains terms that:
 - Have multiple accepted definitions, the context does not help clarify which definition is correct, and we need to specify which definition is acceptable.
 - Are unique to UNOS/OPTN and therefore there isn't another definition available to the public. We tried to coordinate the terms between NOTA, the Final Rule, and the OPTN Bylaws.
- The administrative rules regarding variances moved from current Policies 3.1 and 3.4 into this Policy. Note that we created subsections after each of the organ-specific, allocation policies for variances. When the Board adopts new variances, we'll place them in the relevant organ specific Policy.
- Similarly, emergency procedures and the Dept. of Defense directive moved here from current Policy 3.4 because these are overarching and more administrative in nature. Combined, the policies concerning variances, emergencies, and the DoD directive are three situations when a Member might not be required to comply with the regular OPTN/UNOS Policies.

- **Policy 2: Organ Procurement**

This Policy mostly came from the current Policy 2. Very little of the current Policy 2 did not remain in the rewritten Policy 2. However, several other policies were moved into the rewritten Policy 2. This largely includes the donor information which previously resided in the organ specific policies (3.5 – 3.11). Some other changes include:

- Donor information was consolidated into one place so that OPOs could reference one Policy instead of the various organ-specific Policies. It also highlights similarities and differences across organs making policy decisions more apparent.
- The donor information section was split into required and requested sections. Committees will determine whether these are requirements, recommendations, or requirements under certain conditions.

- **Policy 3: Candidate Registrations, Modifications, and Removals**

This Policy largely came from the current Policy 3.2. The current Policy 11 was also moved here since the registration fee is most relevant at the time of candidate registration.

- **Policy 4: Histocompatibility**

This is a new Policy that consolidates the various histocompatibility requirements that are in the Bylaws and Policies. During the OPTN Bylaws Rewrite, much of this material moved from the Bylaws to Policy. Other significant sources for this material were Appendices 3A and 3D of the current Policies. Note that much of this language remains the same as that in the current Policies since all the histocompatibility policies are currently undergoing a major rewrite by the Histocompatibility Committee that is slated to go out for public comment in Fall 2013. This rewrite by the Histocompatibility Committee, if approved by the Board, will largely replace this Policy 4.

Readers will also see a new layout for the equivalency tables; reviewers and the committees found the new layout to be more user friendly.

- **Policy 5: Organ Offers, Acceptance, and Verification**

This Policy largely came from the current Policy 3.3. Acceptance and screening criteria were moved here from the various organ specific Policies (3.5 – 3.11). There was already some general acceptance and screening criteria Policies and this combines it with the organ specific criteria. Some other changes include:

- The order of allocation section combines several different policies into one list.
- The rules regarding the allocation of other organs were moved here from current Policy 3.9. These policies have never been used and are in the parking lot for further review.

- **Organ Allocation Policies (Policies 6-11)**

The organ allocation policies were refocused on allocation requirements. This means that organ specific rules that are not directly related to allocation were moved to other policies. For example, donor information and candidate acceptance criteria were moved out of the allocation policies and into other policies. There proposed policies will also have a common structure. This will help facilitate cross-organ discussions and ensure more uniformity in policy interpretations.

Further, the organ allocation policies are in alphabetical order by the name of the organ. Finally, some placeholder policies were reserved (Policy 12) for future allocation policies such as VCA. This way, there won't be a need to renumber the policies again if additional allocation policies are created.

- **Policy 6: Allocation of Hearts and Heart-Lungs**

This Policy largely came from current Policy 3.7. The current Policy 3.7 contains rules regarding hearts and lungs. While one Committee oversees both sets of organ policies, and there exists overlap in the personnel and expertise, the two organ systems have different approaches to organ allocation and therefore different rules. For this reason, the two organs are split into different policies in the rewrite. Heart donor information was moved to the new Policy 2.

- **Policy 7: Allocation of Intestines**

This Policy largely came from current Policy 3.11. Intestine donor information was moved to the new Policy 2.

- **Policy 8: Allocation of Kidneys**

This Policy largely came from current Policy 3.5. Because the rewrite uses the last version of the policies adopted by the Board, it uses the new Kidney Allocation System (KAS) that was adopted at the June 2013 Board meeting. Kidney donor information was moved to the new Policy 2.

- **Policy 9: Allocation of Livers and Liver-Intestines**

This Policy largely came from current Policy 3.6. Liver donor information was moved to the new Policy 2.

- **Policy 10: Allocation of Lungs**

This Policy largely came from current Policy 3.7. That Policy contains rules regarding hearts and lungs. While one Committee oversees both sets of organ policies, and there exists considerable overlap in the personnel and expertise, the two organ systems have different approaches to organ allocation and therefore different rules. For this reason, the two organs are split into different policies in the Rewrite. The organ allocation policies are in alphabetical order by the name of the organ; therefore, heart allocation is before intestines, etc. Lung donor information was moved to the new Policy 2.

- **Policy 11: Allocation of Pancreas, Kidney-Pancreas, and Islets**

This largely includes the old Policy 3.8. Pancreas donor information was moved to the new Policy 2.

- **Policy 12: *Reserved***

For future VCA allocation policies, according to recent OPTN Final Rule amendment. See <https://www.federalregister.gov/articles/2013/07/03/2013-15731/organ-procurement-and-transplantation-network>.

- **Policy 13: Kidney Paired Donation (KPD)**

This Policy came, mostly unchanged except for minor plain language changes, from the newly approved KPD Policies that went into effect in February 2013.

- **Policy 14: Living Donation**

This Policy came from current Policy 12. The policies concerning kidney informed consent and medical evaluation were restructured to ease future requirements for other living donor organs. While not as prevalent as living kidney donation, there are living donations besides kidney: liver, lung, and pancreas. Eventually, the medical evaluation and informed consent policies will contain information for these other organs. Therefore, they were restructured to enable the addition of these policies in the future.

- **Policy 15: Identification of Transmissible Diseases**

This Policy came from the current Policy 4.

- **Policy 16: Organ and Vessel Packaging, Labeling, Shipping, and Storage**

This Policy came from the current Policy 5 and Policy 12. The current Policy 12 largely restates the packaging and labeling requirements for deceased donors. There are some slight differences but the requirements are largely uniform between deceased and living donors. One of the principles of the Rewrite was to avoid repeating large amounts of information. Therefore, we moved the information from Policy 12 into the new Policy 16, adding sections as necessary to highlight the different requirements for living donor organs.

- **Policy 17: International Organ Transplantation**

This Policy came from the current Policy 6.

- **Policy 18: Data Submission Requirements**

This is largely the old Policy 7. Many terms moved to the definitions section of Policy 1.

- **Policy 19: Data Release**

This Policy came from the current Policies 9 and 10. The previous version of the Rewrite that went out for public comment contained the substantive rewrite of those policies that was out for public comment. That proposal was not adopted by the Board and the committees are working on a replacement. Because a

substantive proposal concerning these policies is pending, this Policy did not receive very many changes in the Rewrite. Instead, it combined current Policies 9 and 10 and made minor updates to the terminology.

- **Policy 20: Travel Expense and Reimbursement**

This Policy came from the current Policy 11. This Policy recently went out for public comment and did not receive very many changes in the Rewrite. This Policy contains one of the few differences between the OPTN and UNOS versions of Policy: the OPTN does not reimburse for alcoholic beverages whereas UNOS will.

To Address after the Rewrite:

Suggested Substantive Changes to Policy (*The Parking Lot*)

During the development and review of this proposal, many reviewers commented on the need to make substantive updates to the policies. One of the goals of this project has been to avoid making substantive changes to the policies. Requests for substantive changes are being handled in several ways:

1. There were some Policy sections that could not easily be written into plain language without making substantive changes. These policies had numerous nuances that hampered standardization in processes and policy language. Committees sponsored and the Board approved public comment proposals to update these Policy sections. (See [Proposal to Clarify and Improve Variance Policies](#) and [Proposal to Clarify Requirements for Waiting Time Modification Requests](#).) Committees continue to work on some of these policies. For example, the Thoracic Committee is working on a substantive rewrite of the Policy 6.5.E: *Heart-Lung Allocation*; the current Policy has some vagueness and different interpretations in the community. Policy 6.5.E: *Heart-Lung Allocation* – This Policy currently has some vagueness, has different interpretations in the community, and is the subject of an existing committee project to refine and update the Policy.
2. There are other Policy sections that have not been updated in several years and need to be updated. Similar to above, these substantive changes will follow the normal policy development process through the Committees and public comment. The Histocompatibility Committee is working on updates to the histocompatibility policies. In spring 2012, the POC released for public comment a [Proposal to Update Data Release Policies](#). The Committees will continue their work to update the data release policies.
3. Other frequent comments concerned recommended actions: what members *should* do, are *highly encouraged* to do, are *recommended* to do, must *try* to do, or are *desired* to do. The Committees discussed whether these could be changed to requirements (by using *must* in the phrase), but determined that would require a substantive change to the Policies. The Committees also discussed moving these items from Policy into an educational or guidance document. Instead, the Committees decided to take a two step approach. This plain language proposal standardizes the phrasing (consistently using *should* instead of the list of phrases above). Next, the Committees will review each of these *shoulds* and determine whether the Policy should be a requirement, be moved to an educational or guidance document, or be made a requirement under defined circumstances.
4. The policies use phrases such as “review” and “verify” that have multiple meanings to different audiences. If there is a requirement in Policy to *review* something, there should be an explanation about the standard to be used and what will happen with the review. The transplant hospital *must verify* the donor vessel’s... *Verify* is also a vague term. To some readers, *verify* means compare two documents and ensure that they match. To other reads, *verify* means to run a separate test to confirm the results.
5. Some policies are very specific about when certain actions must occur (ex. before anastomosis) while other, similar policies are not specific. *Several, periodic, immediately, and timely fashion*– These does not convey precise timeframes.
6. Donor Information – The Rewrite consolidates the list of donor information that OPOs must provide. By consolidating this information, it became apparent that the list of information is not consistent across organs.
7. There are inconsistencies between similar policies for different organs. (Ex. review board operations and donor information.)

8. There are some policies that haven't kept pace with changes in community practice. For example, Policy 2.9: *Requested Organ Specific Information* mentions a *wedge biopsy* but some OPOs would rather use a *needle biopsy*. The committees will follow the normal policy development process to update any of these policies.
9. The rewritten policies reflect the same rules and requirements found in existing policies and were not updated to reflect differences in practices. There were a few situations where the prevailing interpretation of a policy did not match the Policy language. Similar to above, these differences were added to the parking lot to be sent to the committees to determine the appropriateness of updating the policies. Examples include: Policy 2.9: *Requested Organ Specific Information*, which mentions a *wedge biopsy* but some OPOs would rather use a *needle biopsy*.
10. Reviewers questioned whether additional information that is accepted in the community should also be included in the Policies. For example, the Review Board Guidelines, approved variances, or additional sorting criteria used in the match system. The match system uses additional sorting criteria that are not in the organ specific policies.

The committees will work on addressing these items through the normal policy development process. This will include committee deliberation, collaboration with others, public comment, and Board consideration, before substantive changes are made.